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Subject: OCSPP News for January 5, 2021
Attachments: Inside TSCA Newsletter 1.4.pdf

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- Bergson & Campbell PC 1/4; [EPA Publishes Final Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos](#)

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EPA Restricts How Science Can Be Used to Shape Regulations

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Stephen Lee, Bloomberg Law

<https://news.bloomberglaw.com/environment-and-energy/epa-narrows-how-future-administrations-can-use-science-in-rules>

Narrowing the science underpinning EPA regulations should make the agency's rules more defensible, removing judges from disputes about the validity of research, the agency's chief said.

Wheeler unveils final rule to limit agency's use of science. The Environmental Protection Agency rule, released Tuesday (RIN:2080-AA14), would restrict the agency's ability to use scientific studies that include patients' private medical data when issuing regulations. It's a sharp break from its decades-old approach to new rules, which relied on those kinds of studies to issue some of its most expansive regulations, including air quality standards for fine particle pollution.

EPA Administrator Andrew Wheeler defended the new rule, called the Strengthening Transparency in Regulatory Science, as a win for "sunshine" in regulations.

The rule would get judges "out of the habit of making scientific determinations for the agency," and cut back on litigation, Wheeler said at a web briefing hosted by the Competitive Enterprise Institute, a libertarian nonprofit.

But the rule, which takes effect immediately upon publication in the Federal Register on Wednesday, is expected to lead to immediate legal challenges. President-elect Joe Biden also is expected to seek to reverse the measure, but writing a new regulation would take years.

"This rule would bar regulators from considering bedrock scientific evidence about the dangers of pollution," Richard Revesz, director of the Institute for Policy Integrity at the New York University School of Law, said in a statement.

Limited Exemptions

Wheeler said the rule wouldn't categorically rule out any scientific studies; any future administrator could still use pivotal studies if the underlying information isn't publicly available, as long as an explanation is provided.

He said he imagines the exemption will be used "sparingly." Under the rule, the EPA must give greater consideration to studies whose underlying dose-response data is publicly available for independent validation.

But to critics, the new approach makes it harder for future administrations to issue new standards by severely narrowing the kinds of data the agency can draw upon.

In May, dozens of science groups, representing most of the American scientific consensus, told Wheeler that the rule would diminish the agency's ability to regulate contaminants in water, air, and land.

'Smoke-Filled' Room

Betsy Southerland, former director of EPA's Office of Water who left the agency in 2017, said in a statement that the EPA is now "the only agency in the federal government unable to base rules and guidance on public health studies unless participants' private information is made publicly available."

But Wheeler shot back at critics, saying that "I believe a number of the critics are very cynically trying to kill this effort because they prefer the agency to make decisions in a proverbial smoke-filled back room, where they don't have to explain how the agency reached a particular decision on a pesticide or chemical."

Wheeler sought to cement the rule on the books, stating on Tuesday that it isn't subject to being overturned by Congress through the Congressional Review Act—which gives lawmakers 60 days after a rule takes effect to vote to strike it down.

That's because it's "an internal housekeeping regulation that does not affect external people to the agency," and because it isn't economically significant, meaning it isn't expected to have an annual effect on the economy of at least \$100 million, he said.

(Revises with additional comments from Wheeler.)

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Wheeler unveils final rule to limit agency's use of science

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Kelsey Brugger, E&E News

<https://www.eenews.net/greenwire/2021/01/05/stories/1063721819>

The Trump administration, during its last days in power, fired another shot in its war on regulations and science-based policies, rewriting the rules on the use of scientific research at EPA.

The agency today announced its final Strengthening Transparency in Regulatory Science action, which critics say aims to weaken future air pollution and water regulations by limiting the use of research that relies on medical records or other private data.

It's a long-standing Republican idea that the Trump EPA has worked on for years, even in the face of overwhelming criticism from public health and environmental experts.

EPA Administrator Andrew Wheeler has continually hyped the rule as a way to "prioritize transparency" and "increase opportunities" for public involvement.

"Why would anyone want our decisions to be made in secret?" Wheeler said this morning at a virtual event hosted by the Competitive Enterprise Institute, a free-market think tank.

"This empowers the American people to demand future transparency from this agency going forward," Wheeler said about the new rule.

Wheeler said he signed the transparency rule last Wednesday and that it will be published tomorrow in the Federal Register.

As with other recent actions, EPA claimed "good cause" for the rule to take effect immediately, potentially opening it up to additional legal challenges.

'Listened to the concerns'

The announcement today comes as the agency seeks to rush several rules in the eleventh hour of the Trump administration. Other notable recent actions include air quality standards on ozone and soot, a cost-benefit analysis rewrite for air regulations and a rule on greenhouse gas emissions from airplanes.

The transparency rule has proved to be among the agency's most controversial, in part because it would affect public health protections as the COVID-19 pandemic continues. Had the rule already applied to the Food and Drug Administration, the coronavirus vaccines would never have been approved, former EPA attorney Kevin Minoli has argued.

The final EPA rule requires the agency to give more weight to studies for which the underlying "dose-response" data is publicly available. Dose-response is essentially the amount of a pollutant's negative impact on public health.

Although the rule doesn't force EPA to outright ban the use of nonpublic scientific research, it requires the agency to give those studies "lesser consideration."

"We listened to the concerns people had," Wheeler said, adding, "There is no study that will automatically be cut out from review going forward."

Wheeler specifically pointed to the famous 1993 Harvard Six Cities study, which was instrumental in creating federal air pollution regulations.

Reaction

In effect, however, the rule aims to restrict research that relies on medical records or other data that cannot be made public due to privacy laws.

Critics said the final text sets up a vague and complicated process for the incoming Biden administration, which is expected to repeal it or refuse to defend it in the face of numerous expected legal challenges.

The Biden transition team would not address this specific rule but said last week that it plans to issue a memo to "freeze" a bevy of Trump actions.

The rule also gives the EPA administrator discretion "in the event there is a pivotal study that is really fundamental to a regulation," Wheeler said. Critics see political meddling.

"At best, it's going to be confusing," said Chris Frey, a professor at North Carolina State University who was a member of the EPA science advisory board. "The fact that these studies don't provide data for recalculation — how would that work in a regulatory framework? That kind of vague language seems to key up endless lawsuits."

In another change, the final rule does not apply retroactively. However, it would apply to EPA actions like the national air quality standards for soot, which are updated every five years.

An onslaught of criticism from public health and scientific organizations has abounded since Wheeler announced the final rule last night in a Wall Street Journal op-ed.

Betsy Southerland, a former longtime EPA official who resigned to protest the administration's actions at the agency, said the rule achieves "the goal of climate deniers and industry polluters."

Harold Wimmer, national president of the American Lung Association, said thousands of lives are saved each year because "EPA has been able to use the best science to set air pollution standards."

Over the summer, doctors took time out of treating patients with COVID-19 to publicly urge EPA to abandon its effort. In a virtual video event, Lisa Patel, a doctor at Stanford Children's Health, said EPA "would create its own public health crisis with this rule" (Greenwire, April 15, 2020).

The Environmental Defense Fund issued a press release calling the rule "a nasty parting shot from an administration that has undermined science and jeopardized our foundational environmental and public health protections from its beginning."

The group called on the Biden team to add the issue to its "long and growing list of bad policy decisions" from the Trump era. And the Union of Concerned Scientists has already said it's ready to sue.

Congressional reaction

On Capitol Hill, Sen. Tom Carper (D-Del.), ranking member of the Senate Environment and Public Works Committee, has consistently voiced opposition to the effort, and his staff has said Congress could possibly use the Congressional Review Act to quickly kill the rule. The law allows lawmakers and the White House to ax rules that have been finalized within 60 congressional days.

But today, Wheeler claimed the transparency rule is exempt from the Congressional Review Act because it is an internal procedure that relies on the housekeeping statute. At the same time, Wheeler has said the rule gives the public a new avenue to challenge agency decisions. Critics said he can't have it both ways.

"So much for this Trump @EPA Censored Science rule being just a matter of internal agency procedure, not affecting the rights or obligations of 3rd parties," tweeted Natural Resources Defense Council air and climate advocate John Walke. "@EPAAWheeler can't help revealing dirty little secret behind its act of sabotage against the incoming Biden Administration."

Rep. Frank Lucas (R-Okla.), ranking member of the House Science, Space and Technology Committee, said, "Transparency is essential to the scientific process and the foundation of public trust in policy decisions. This final rule allows for underlying data to be securely validated and evaluated by subject matter experts."

Sen. Sheldon Whitehouse (D-R.I.) said, "This scheme is corrupt, crooked and cynical. Its purpose is to eliminate public health science by threatening disclosure of private health information. It's a page ripped straight from the science denial playbook of the tobacco and lead paint industries. If capable of shame, the polluter toadies leading Trump's EPA should be ashamed."

Gretchen Goldman, a scientist at UCS, said the rule places a "tremendous burden" on researchers, "who now must go to great lengths to pass their data, methods, models, details to anyone who asks for it, after running the gantlet of peer review, if they want their work to inform EPA."

Yet many proponents of the rule might be disappointed that it does not go far enough, said Myron Ebell, director of energy and environment issues at the Competitive Enterprise Institute. But he called it an important incremental step.

Many recent epidemiological studies are arguably transparent even under this final rule, said Frey, the North Carolina State professor. A recent Harvard University study, for instance, has a sample size of more than 60 million people — much bigger than the Six Cities study.

He explained that the scientific community has been grappling with the issue of transparency and reproducibility for years. But this rule, he asserted, does not accomplish anything.

"It's not going to help or improve scientific rigor," Frey said. "The bottom line is, EPA didn't do any analysis, so this is just arm-waving."

Chemical measures enacted as Congress overrides Trump's NDAA veto

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Inside EPA

<https://insideepa.com/tsca-takes/chemical-measures-enacted-congress-overrides-trump-s-ndaa-veto>

Owens Sees Biden EPA Using Asbestos Precedent To Revisit Evaluations Congress has enacted policies barring military procurement of certain items containing per- and polyfluoroalkyl substances (PFAS), bolstering federal PFAS research and creating a first-time federal sustainable chemistry program when lawmakers voted late last week to override President Trump's veto of defense authorization legislation.

The Senate Jan. 1 voted 81-13 to override Trump's veto of the fiscal year 2021 defense authorization act (NDAA), days after the House voted 322-87 to override the veto.

The override marked the first such congressional pushback of a Trump veto and cleared the way for the Biden administration to implement the new chemical policy provisions.

These include measures which would bar the Defense Logistics Agency (DLA) from procuring certain products containing perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), and create an interagency body led by the White House Office of Science and Technology Policy (OSTP) to coordinate federal PFAS research and craft a federal action plan to identify and address research gaps pertaining to the chemicals.

Other PFAS provisions in the bill include the establishment of a prize for innovative research that results in a replacement firefighting foam that does not contain PFAS; a requirement for DOD to survey and report on firefighting equipment technology that will help phase out PFAS; the establishment of an interagency body to coordinate PFAS research; and the authorization of \$1.4 billion for environmental remediation, including for PFAS.

The NDAA also includes legislation long pushed by Sen. Chris Coons (D-DE) that requires OSTP, together with officials from EPA and several other agencies, to create an interagency group “with responsibility to coordinate federal programs and activities” in support of “sustainable chemistry.”

Senate Armed Services Committee Chairman Jim Inhofe (R-OK) applauded the veto override, saying in part that it would bolster efforts to develop safer chemicals in the future by “accelerating innovation into the technologies that will keep our children’s children safe,” he said in a Jan. 1 statement.

Trump had threatened to veto the \$740 billion bill over a number of provisions, putting into jeopardy the PFAS provisions which Congressional supporters had fought to keep in the bill.

But a successful veto was unlikely, as the bill had initially passed Congress with a veto-proof majority in both chambers. In his veto message, Trump had listed a series of grievances with the NDAA, including language renaming bases that are currently named after Confederate generals, limiting the use of military funds for border wall construction, limiting the executive’s ability to withdraw troops stationed overseas and Congress’ failure to eliminate section 230 of the Communications Decency Act.

Owens Sees Biden EPA Using Asbestos Precedent To Revisit Evaluations

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Inside EPA

<https://insideepa.com/tsca-news/owens-sees-biden-epa-using-asbestos-precedent-revisit-evaluations>

Former Obama toxics chief Steve Owens says the new Biden administration could use the Trump EPA’s “supplemental” evaluation of asbestos as a precedent for similar moves on other chemicals, giving officials an avenue to tighten several TSCA reviews that environmentalists say ignored significant risks and exposure pathways.

Chemical Makers Get Second Shot to Protect Trade SecretsIn an exclusive interview with Inside TSCA, Owens -- now a partner at the law firm Squire Patton Boggs -- says the asbestos evaluation, which EPA plans to advance in 2021, sets a precedent that could allow the incoming administration to revisit other Trump-era chemical evaluations even after the agency finalizes its first slate of 10 risk reviews as it plans to do before President-elect Joe Biden takes office on Jan. 20.

“There’s a good likelihood that there will be not necessarily do-overs but go-backs on the first 10,” Owens says.

He continues that supplemental evaluations would give the Biden EPA an opportunity to “take a much broader focus on the conditions of use for those substances,” expanding the Trump administration’s narrowly tailored reviews. In particular, it would allow officials to reverse decisions not to consider exposure pathways that could be regulated through other statutes, such as air emissions potentially subject to the Clean Air Act’s air toxics program.

Democrats and environmentalists have generally attacked that position -- that TSCA is a “gap-filling statute” and should only address risks outside the scope of other laws -- as untethered from the statute’s text and called on Biden to revise evaluations based on that principle or even restart them from scratch.

And Owens says that EPA’s decision to craft a supplemental evaluation of asbestos to consider the substance’s legacy uses, separate from the recent final evaluation widely attacked as too narrow, sets a precedent that Biden officials will be able to build on in order to revisit other evaluations.

“That’s not anywhere in the statute” but EPA is moving forward with the second evaluation nonetheless, meaning the next administration could cite that action to justify a similar process on other chemicals, he says.

For example, environmentalists have already suggested that EPA take such an approach with its pending evaluation of pigment violet 29 (PV29) -- the last of the first batch of 10 the agency is scrambling to complete.

In recent comments on a revised draft PV29 evaluation, the group Safer Chemicals, Healthy Families (SCHF) urged officials to quickly finalize unreasonable risk findings based on existing data regarding known adverse effects but then conduct a supplemental evaluation to address additional health endpoints based on new data the group wants EPA to order producers to provide.

Acknowledging that this additional testing may further delay the assessment's completion, SCHF suggests that EPA "finalize unreasonable risk determinations for PV29 based on the known lung toxicity and carcinogenicity of the carbon black surrogate" as described in the existing second draft evaluation. "Once this testing is completed, a supplemental risk evaluation and/or additional risk management may be warranted," SCHF adds.

The agency could apply a similar approach to other recently finalized evaluations, including, for example, its just-completed evaluation of 1,4-dioxane, which industry, states and environmentalists have all criticized.

'More Aggressive Posture'

Owens says supplemental evaluations will be part of a range of options incoming Biden officials could deploy to tighten their predecessors' findings, which could also come through the process of writing risk-management rules that will be due two years after each final evaluation -- meaning they will arrive between late 2022 and early 2023.

"I think you will see a more aggressive posture from that program office in a number of different ways" after Biden takes office, Owens says.

And he says that along with the debate over TSCA's "gap-filling" nature, officials will also likely look to expand the reviews' consideration of potentially exposed or susceptible subpopulations, including fence-line communities, minorities, Native Americans and indigenous peoples and lower-income populations, in line with Biden's general focus on environmental justice.

The reformed TSCA law requires EPA to consider risks to vulnerable communities in its chemical evaluations and risk-management rules, but so far the agency has yet to identify any such risks in its reviews.

EPA could also face calls to rework its Dec. 21 rules limiting use of five chemicals it identified as persistent, bioaccumulative and toxic (PBT), because they include several broad exemptions for certain industries or uses.

"To really have addressed the spirit of [TSCA], they should have been broader in their applicability. There should have been few if any loopholes, to use that word," Owens says.

Since PBT chemicals are singled out in the toxics law as the most dangerous to health and the environment, he continues, the rules governing their use set a precedent for future risk-management policies. "If this is what you're going to do with the worst of the worst, then what are you going to do with the others?"

There will also be continuing pressure on the toxics office to address per- and polyfluoroalkyl substances (PFAS) through TSCA, including by issuing risk-management regulations outside the usual evaluation process. "This is a significant enough problem that the agency needs to move aggressively on it," Owens says.

He suggests that the toxics office could take a leading role on PFAS because the chemicals are a cross-media concern that other programs have not addressed aggressively. "If the water office is not going to do that, then the TSCA program should."

Moreover, he says, TSCA provides a long list of authorities EPA can use to get more data on PFAS hazards and take quick action. "There's a whole array of authorities that EPA has that they should be utilizing to address PFAS."

In general, Owens says, rather than being limited by EPA's statutory authority, the most significant constraints on those actions are likely to be the result of limited staffing and other resources. "Certainly there's a lot of options that the new administration will have. The big issue is going to be resources and bandwidth."

Not only will the agency be under pressure to move quickly on both the 10 risk management rules and the next round of 20 new evaluations, Owens says, but it will face the challenge of quickly staffing up the toxics office in order to reach the capacity needed to meet those targets, either by hiring new staff or drawing from other programs.

Litigation

In addition to whatever changes the Biden EPA voluntarily makes to the TSCA program, ongoing and threatened court cases could rewrite the agency's authority under TSCA or force it to make targeted changes to specific rules. "There's a lot of litigation out there right now," and the number of suits will only grow as stakeholders challenge the 10 recent evaluations, PBT rules and other policies, Owens says.

Along with litigation over individual actions, he adds, environmental groups and Democrats will likely seek to test EPA's general practice of narrowly tailoring its chemical evaluations and risk management rules -- tests that may have already begun in pending litigation over EPA's findings on methylene chloride and other chemicals.

"This is a very important lawsuit [that will determine] what kind of authority EPA has under TSCA," one industry attorney has said of the methylene chloride litigation *Neighbors For Environmental Justice, et al., v. EPA*.

It will show whether "TSCA is a gap-filling statute, which is what the legislative history says, or is it intended to supplant" other environmental statutes, the source added.

The eventual ruling in such a case could result in a new precedent that might render several Trump-era policies unlawful -- along the lines of the U.S. Court of Appeals for the 9th Circuit's 2019 decision requiring EPA to consider legacy uses in evaluations -- or bar any attempt at stricter regulation, which would force the Biden administration to rework its approach to TSCA, possibly years into the term.

EPA could also seek settlements or voluntary remands in cases that are ongoing when Biden takes office on Jan. 20, setting up structured deadlines for reconsidering Trump-era rules and avoiding the possibility of unexpected decisions on several issues. But Owens says even in those cases it will be important for stakeholders to scrutinize the courts' orders closely to understand exactly what steps the agency is committing to take.

New Chemicals

Separate from the cycle of evaluations and risk-management rules for existing chemicals, the Biden EPA will also face "countervailing pressures" to rework the Trump-era approach to new chemicals -- an approach Owens says has left all sides unsatisfied as the agency has struggled to meet TSCA's 90-day deadline to conduct pre-market reviews of new chemicals under section 5 of the law.

In particular, Owens says, industry appears to have shifted its priority from limiting disclosure of confidential business information to speeding the review process even if that requires more disclosures to EPA. "There has been a little bit of whiplash" from that shift, he says.

More information on new chemicals could also help EPA avoid issuing significant new use rules (SNURs) that industry sees as unworkable.

"They're issuing a ton of SNURs and it's creating some confusion on both sides . . . a lot of companies are not quite sure what to do with a substance that's been approved but has significant restrictions on it," he says.

Owens expects that EPA will revise its section 5 policies to seek more data at the start of the review process "so they don't have to engage in all this guesswork" or "back and forth" with companies about the potential health and environmental effects of a substance. -- David LaRoss (dlaross@iwpnews.com)

Chemical Makers Get Second Shot to Protect Trade Secrets

- Pat Rizzuto, Bloomberg Law

<https://news.bloomberglaw.com/environment-and-energy/chemical-makers-get-second-shot-to-protect-trade-secrets?context=search&index=0>

The EPA is giving chemical manufacturers another chance to revise their requests to keep secret the details of chemicals they make or import.

The Environmental Protection Agency released a final rule (RIN 2070-AK24) Tuesday reopening a 2017 procedural regulation that allowed chemical manufacturers to shield from the public and competitors the specific identity about certain compounds.

Specific chemical names are like blueprints providing the structure, source, and other details about how the chemical is produced. That makes specific chemical identities vital proprietary information that chemical manufacturers safeguard.

Chemical manufacturers will have 60 days to remedy errors made on their requests to designate their chemicals' identities as confidential business information, or CBI. That means the EPA would know what specific chemical is being made or sold in the U.S., but the general public—including competitors—would know only a generic name.

The agency's final rule justified the move as a way to alleviate chemical manufacturers confusion about how to make and justify their CBI claims.

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US EPA finds asbestos presents unreasonable risk across multiple uses

- Terry Hyland, Chemical Watch

<https://chemicalwatch.com/198284/us-epa-finds-asbestos-presents-unreasonable-risk-across-multiple-uses>

The US EPA has concluded that chrysotile asbestos poses an unreasonable risk to workers, occupational non-users, consumers and bystanders, setting up a two-year process for the agency to finalise a rule to safeguard against those risks.

A final risk management rule could bring worker safety measures and other requirements for the chlor-alkali industry – which uses chrysotile asbestos to create semipermeable diaphragms to make chlorine – as well as the oil and automotive sectors that use the fibrous substance for certain applications.

In its final TSCA risk evaluation, published on 4 January in the Federal Register, the EPA confirmed many of the preliminary findings from its March 2020 draft evaluation of the substance, identifying cancer risks from inhalation exposure in half of the conditions of use (CoUs) examined.

The agency evaluated 32 conditions of use (CoUs) across six categories where the substance is currently used: chlor-alkali diaphragms, sheet gaskets, other gaskets, oilfield brake blocks, aftermarket automotive brakes/linings and other vehicle friction products.

It said workers face unreasonable risks in the following applications:

- processing and industrial use of diaphragms in the chlor-alkali industry;
- processing and industrial use of sheet gaskets used in chemical production;
- industrial use and disposal of brake blocks in the oil industry;
- commercial use and disposal of aftermarket automotive brakes/linings;
- commercial use and disposal of other vehicle friction products; and
- commercial use and disposal of other gaskets.

It also concluded that chrysotile asbestos presents an unreasonable risk to consumers and bystanders in two CoUs:

- aftermarket automotive brakes and linings; and
- other chrysotile asbestos-containing gaskets.

Similar to its draft findings, the EPA said that the following CoUs do not trigger concerns of unreasonable risk:

import of chrysotile asbestos and such-containing products;
distribution of chrysotile asbestos-containing products;
use of such-containing brakes for a specialised, large National Aeronautics and Space Administration (Nasa) transport plane known as the 'Super Guppy'; and
disposal of such-containing sheet gaskets processed and/or used in the industrial setting and asbestos-containing brakes for Nasa's Super Guppy plane.

The agency also concluded that asbestos does not pose an unreasonable risk to the environment, saying there is "low or no potential" for risk to aquatic or sediment-dwelling organisms.

It now has one year to propose regulations to mitigate identified risks and one additional year to finalise any rules.

Legacy uses

The EPA focused its finalised TSCA risk evaluation – which it referred to as 'part 1' of the review – on 'ongoing uses' of chrysotile asbestos. It excluded legacy uses that have been phased out as well as uses of the other five fibre forms of asbestos – crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite and actinolite.

Part 2 of the TSCA risk evaluation for asbestos will focus on those legacy uses and associated disposals, including the five other fibre types, the EPA said.

The draft scope document for this will be released in 'mid-year 2021', it said.

The split review follows a 2019 federal court ruling that said the agency had erred by not including legacy uses and their associated disposal in the scope of its TSCA risk evaluations.

The Asbestos Disease Awareness Organization (ADAO) was quick to criticise the agency's decision to address asbestos' legacy issues in a supplemental review, saying it will delay any potential response to limit exposure in other areas.

ADAO co-founder and president Linda Reinstein said the EPA "has issued a piecemeal and dangerously incomplete evaluation that overlooks numerous sources of asbestos exposure and risk, and understates the enormous toll of disease and death for which asbestos is responsible".

The agency failed to assess asbestos contamination in consumer and industrial products containing talc, the group said. Asbestos can develop naturally alongside talc in rock deposits and has been found as a contaminant in a number of talc-based products in recent years.

The scope of information the EPA used in its review was also at the centre of a recent court ruling in which the agency was ordered to close the 'loopholes' in its asbestos reporting. ADAO counsel Robert M Sussman said the December ruling made it clear that the "EPA lacks a sound understanding of the risks presented by asbestos".

Consumer uses of 1,4-dioxane cleared in final TSCA risk evaluation

- Terry Hyland, Chemical Watch

<https://chemicalwatch.com/198439/consumer-uses-of-14-dioxane-cleared-in-final-tsca-risk-evaluation>

The US EPA has concluded that 1,4-dioxane poses an unreasonable risk to workers working directly with the solvent in more than half of the conditions of use (CoUs) evaluated. But it said the substance does not present a risk of injury to consumers, occupational non-users (ONUs), bystanders or the environment.

The finalised TSCA risk evaluation – released on 31 December – incorporates both the agency's June 2019 draft findings of dermal and inhalation risks to workers, as well as its supplemental findings from November that 1,4-dioxane does not present a risk to the general population when present as a byproduct in certain consumer items, uses that were excluded from the draft review.

The agency will now start the two-year process to develop a rule to mitigate the risks to workers. It has one year to propose it and a further year to finalise it.

The 13 CoUs presenting an unreasonable risk to workers fall across four categories. They are:

manufacturing:

domestic manufacture;

import/repackaging;

processing:

repackaging;

recycling;

non-incorporative;

processing as a reactant;

industrial/commercial uses:

intermediate;

processing aid;

laboratory chemicals;

adhesives and sealants;

printing and printing compositions;

dry film lubricant; and

disposal.

Potential injuries to workers include liver toxicity, olfactory epithelium effects, and cancer resulting from acute and chronic inhalation and dermal exposures, the EPA said.

An additional 11 CoUs do not present a risk of injury to human health or the environment, it concluded. These are:

distribution in commerce;

industrial/commercial uses:

functional fluids, open system;

other uses – spray polyurethane foam;

consumer uses:

arts, crafts and hobby materials – textile dye;

automotive care products – antifreeze;

cleaning and furniture care products – surface cleaner;

laundry and dishwashing products – dish soap;

laundry and dishwashing products – dishwasher detergent;

laundry and dishwashing products – laundry detergent;

paints and coatings – paint and floor lacquer; and

other uses – spray polyurethane foam.

Complications for states

TSCA generally prohibits, or preempts, states from restricting chemicals subject to 'final agency action' unless they secure a waiver. While the boundaries of federal preemption under the law remain uncertain, they can be triggered by a determination in a final risk evaluation that a substance does not pose an unreasonable risk.

As such, the EPA's finding of no unreasonable risk for consumer uses of 1,4-dioxane – in particular in surface cleaners, detergents and dish soap – could complicate efforts in a state like New York, which is working on rules to restrict levels of the substance in cosmetic and cleansing products.

New York was part of a coalition of 15 state and city attorneys general that submitted comments critical of the EPA's recent decision to add – and clear – consumer uses, calling the action "fatally flawed".

In its final risk evaluation, the EPA said it chose not to consider exposures through drinking water, ambient air or sediment pathways, saying the substance's presence in those media falls under the jurisdiction of other federal laws, like the Safe Drinking Water Act.

TSCA is a 'gap-filling' statute, the agency said, and "it is both reasonable and prudent" to more narrowly tailor risk evaluations under it where other statutes and programmes address exposures.

The American Chemistry Council (ACC) said it "agrees with the EPA's conclusion that 1,4-dioxane exposures do not present an unreasonable risk to consumers". But the trade group added the agency's final evaluation still "significantly overstates the risks".

First ten evaluations almost complete

With the release of the final TSCA risk evaluation for 1,4-dioxane, the EPA has now completed nine of the first ten existing chemicals subject to risk evaluation under the amended law. The agency has also released final risk evaluations for:

methylene chloride;
1-bromopropane (1-BP);
cyclic aliphatic bromide cluster (HBCD);
carbon tetrachloride;
trichloroethylene (TCE);
perchloroethylene (Perc);
n-methylpyrrolidone (NMP); and
asbestos (part 1).

US EPA disregards risk of 1,4-dioxane in drinking water

-
Britt E. Erickson, C&EN

<https://cen.acs.org/policy/chemical-regulation/US-EPA-disregards-risk-1-4-dioxane-in-drinking-water/99/web/2021/01>

Despite numerous requests to extend the comment period for part of its risk evaluation of the solvent 1,4-dioxane, the US Environmental Protection Agency plowed ahead and finalized the assessment late in the day Dec. 31. The hastily compiled analysis, released as a draft supplement Nov. 19, pleased no one, including environmental groups, state attorneys general, and the chemical industry.

The EPA agreed to do the supplemental analysis to expand the scope of its initial draft evaluation, released in June 2019, to include risks to consumers from small amounts of 1,4-dioxane impurities in laundry and dishwasher detergents, paints, and other products, after numerous stakeholders criticized the agency for omitting such uses.

But in that additional evaluation, the EPA still ignored what environmental groups and state attorneys general say is the biggest source of exposure to 1,4-dioxane to the general population—drinking water. Instead, the agency evaluated the risks from recreational activities, such as swimming in water contaminated with 1,4-dioxane. The EPA acknowledges that people may be exposed to 1,4-dioxane via drinking water, as well as from ambient air and soil, but the agency argues that such exposures fall under the jurisdiction of other environmental statutes, not the Toxic Substances Control Act (TSCA). The 1,4-dioxane assessment is one of the first 10 high-priority chemical assessments the EPA conducted under 2016 revisions to TSCA.

The EPA considers 1,4-dioxane "likely to be carcinogenic to humans." The solvent is used to manufacture other chemicals, process food, and produce adhesives and sealants. It is also an impurity in household detergents, cleaners, and personal care products.

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The American Cleaning Institute (ACI), which represents the cleaning products industry, and the American Chemistry Council (ACC), the US chemical industry's main lobbying group, agree with the EPA that trace amounts of 1,4-dioxane impurities in household cleaning products do not pose unreasonable health risks to consumers. Nonetheless, neither group is pleased with the EPA's final assessment.

The ACI is disappointed that the EPA did not evaluate risks to the general population associated with drinking water, as well as risks to workers associated with industrial and commercial cleaning products. The group is concerned that without a federal standard, states will develop a patchwork of different regulations.

The ACC takes issue with changes to the EPA's evaluation of chronic hazards from dermal exposure to 1,4-dioxane. Those changes reduce the acceptable level of dermal exposure by three orders of magnitude, the group states in comments submitted Dec. 10 to the EPA. "By failing to incorporate the best available science, the final evaluation significantly overstates the risks associated with exposure to 1,4-dioxane," the ACC says in a statement.

The EPA did identify unreasonable risks to workers exposed to 1,4-dioxane for 13 of the 24 scenarios that it evaluated. The agency plans to propose regulations within one year to address those risks.

Final Rules from EPA Address Five PBT Chemicals

- Lisa Whitley Coleman, EHS Daily Advisor

<https://ehsdailyadvisor.blr.com/2021/01/final-rules-from-epa-address-five-pbt-chemicals/>

The EPA issued final rules to reduce exposure to five persistent, bioaccumulative and toxic (PBT) chemicals under the Toxic Substances Control Act (TSCA) on December 22, 2020.

"PBT chemicals are of particular concern not only because they are toxic but also because they remain in the environment for long periods of time and can build up or accumulate in the body," according to the EPA press release. "Addressing these chemicals is a critical step in the agency's efforts to protect the health of Americans – including children, workers, and subsistence fishers."

The final rules "limit or prohibit the manufacture (including import), processing, and/or distribution in commerce" of the five chemicals identified for expedited action, which include:

"Decabromodiphenyl ether (DecaBDE): A flame retardant in plastic enclosures for televisions, computers, audio and video equipment, textiles and upholstered articles, wire and cables for communication and electronic equipment, and other applications";

"Phenol, isopropylated phosphate (3:1) (PIP (3:1)): A plasticizer, a flame retardant, an anti-wear additive, or an anti-compressibility additive in hydraulic fluid, lubricating oils, lubricants and greases, various industrial coatings, adhesives, sealants, and plastic articles";

"2,4,6-tris(tert-butyl) phenol (2,4,6-TTBP): An intermediate/reactant in processing, and is incorporated into formulations destined for fuel and fuel-related additives";

"Hexachlorobutadiene (HCBd): A chemical used as a halogenated aliphatic hydrocarbon that is produced as a byproduct during the manufacture of chlorinated hydrocarbons"; and

"Pentachlorothiophenol (PCTP): A chemical used to make rubber more pliable in industrial uses."

The final rules and the EPA PBT website identify the hazards and risk management procedures for these chemicals.

DecaBDE

DecaBDE is toxic to aquatic invertebrates, fish, and terrestrial invertebrates. Data indicate the potential for developmental, neurological, and immunological effects; general developmental toxicity; liver effects; and

carcinogenicity. While many uses of decaBDE have ceased, EPA has concluded that humans or the environment is likely exposed to decaBDE under certain conditions of use.

Acceptable uses include:

Manufacture, processing, and distribution in commerce for use in curtains in the hospitality industry, and the distribution of the curtains themselves, for a period of 18 months, after which the prohibition would go into effect; Processing and distribution in commerce for use in wire and cable insulation in nuclear power generation facilities, and the distribution of the wire and cable insulation that contains decaBDE, for a period of 2 years, after which the prohibition would go into effect;

Manufacture, processing, and distribution in commerce for use in parts for new aerospace vehicles, and distribution in commerce of the new vehicles containing such parts, for a period of 3 years, after which the prohibitions would go into effect;

Manufacture, processing, and distribution in commerce for those aerospace vehicles produced with decaBDE-containing parts, which will be excluded from the prohibition until the end of their service lives; manufacture, processing, and distribution in commerce for use in replacement parts for aerospace vehicles; and distribution in commerce of the replacement parts themselves;

Manufacture, processing, and distribution in commerce for use in replacement parts in motor vehicles, and distribution in commerce of the replacement parts themselves, until the end of the vehicles' service lives or 2036, whichever is earlier;

Distribution in commerce of plastic shipping pallets manufactured before the publication of the final rule that contain decaBDE until the end of the pallets' service lives; and

Processing and distribution in commerce for recycling of plastic that contained decaBDE before the plastic was recycled (i.e., the plastic to be recycled is from articles and products that were originally made with decaBDE), and the articles and products made from such recycled plastic, so long as no new decaBDE is added during the recycling or production process.

PIP (3:1)

PIP (3:1) is toxic to aquatic plants, aquatic invertebrates, sediment invertebrates, and fish. Data indicate the potential for reproductive and developmental effects, neurological effects, and effects on systemic organs, specifically adrenals, liver, ovaries, heart, and lungs.

Acceptable uses include:

Processing and distribution in commerce for use in aviation hydraulic fluid in hydraulic systems and use in specialty hydraulic fluids for military applications;

Processing and distribution in commerce for use in lubricants and greases;

Processing and distribution in commerce for use in new and replacement parts for the aerospace and automotive industries;

Processing and distribution in commerce for use as an intermediate in the manufacture of cyanoacrylate glue;

Processing and distribution in commerce for use in specialized engine air filters for locomotive and marine applications;

Processing and distribution in commerce for use in sealants and adhesives; and

Processing and distribution in commerce for recycling of plastic that contained PIP (3:1) before the plastic was recycled (i.e., the plastic to be recycled is from articles and products that were originally made with PIP (3:1)), and the articles and products made from such recycled plastic, so long as no new PIP (3:1) is added during the recycling or production process.

The EPA is requiring that persons manufacturing, processing, and distributing in commerce PIP (3:1) and products containing PIP (3:1) notify their customers of these restrictions.

The EPA is also prohibiting releases to water from the remaining manufacturing, processing, and distribution in commerce activities and requiring commercial users of PIP (3:1) and PIP (3:1)-containing products to follow existing regulations and best practices to prevent releases to water during use.

2,4,6-TTBP

2,4,6-TTBP is toxic to aquatic plants, aquatic invertebrates, and fish. Surveyed animal data indicate the potential for liver and developmental effects. The EPA has concluded that exposure to 2,4,6-TTBP under the conditions of use is likely.

The EPA is prohibiting the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP at concentrations above 0.3% by weight in any container with a volume of less than 35 gallons in order to effectively prevent the use of 2,4,6-TTBP as a fuel additive or fuel injector cleaner by consumers and small commercial operations (e.g., automotive repair shops, marinas).

The EPA is also prohibiting the processing and distribution in commerce of 2,4,6-TTBP, and products containing 2,4,6-TTBP, for use as an oil or a lubricant additive in concentrations above 0.3% by weight regardless of container size.

HCBD

HCBD is toxic to aquatic invertebrates, fish, and birds and has been identified as a possible human carcinogen. Data indicate the potential for renal, reproductive, and developmental effects.

The EPA is prohibiting the manufacturing (including import), processing, and distribution in commerce of HCBD and HCBD-containing products or articles, except for the unintentional production of HCBD as a by-product during the production of chlorinated solvents, and the processing and distribution in commerce of HCBD for burning as a waste fuel.

PCTP

PCTP is toxic to protozoa, fish, terrestrial plants, and birds. Data for analogous chemicals (pentachloronitrobenzene and hexachlorobenzene) indicate the potential for liver and reproductive effects. However, no animal or human hazard data have been identified.

The EPA is prohibiting the manufacture (including import), processing, and distribution in commerce of PCTP, and products or articles containing PCTP, unless PCTP concentrations are at or below 1% by weight.

Other PBTs

The EPA also announced it had received a manufacturer's request for risk evaluations "for two other PBT chemicals within the octahydro-tetramethyl-naphthalenyl-ethanone (OTNE) chemical category." A public comment period is expected to be announced soon for these two chemicals.

WARD PROVIDES AN UPDATE ON ARKANSAS DICAMBA CUTOFF DATE

- Megan Grebner, Brownfield Ag News for America

<https://brownfieldagnews.com/news/ward-provides-an-update-on-arkansas-dicamba-cutoff-date/>

The Arkansas State Plant Board has kept the cutoff date for dicamba application at May 25th despite a June 30th federal deadline for soybeans.

Arkansas Secretary of Agriculture Wes Ward says they did make some adjustments for some parts of Arkansas. "Those that are inside the levy of the Mississippi River to use the federal label there," he says. "But for the rest of the state it will maintain that May 25th cutoff date."

Ward tells Brownfield the board made the decision early last month. "And give producers and the industry some certainty as they're preparing and planning for the 2021 growing season," he says.

Illinois-specific dicamba restrictions continue in 2021

- Tom Doran, Agri News

<https://www.agrinews-pubs.com/news/science/2021/01/04/illinois-specific-dicamba-restrictions-continue-in-2021/>

The Illinois Department of Agriculture registered dicamba products for use on soybeans in 2021 that includes restrictions that differ from the federal label.

The U.S. Environmental Protection Agency approved five-year registrations Oct. 27 for two over-the-top dicamba products — XtendiMax with VaporGrip Technology and Engenia Herbicide — and extended the registration for an additional OTT dicamba product, Tavium Plus VaporGrip Technology.

The approved federal label includes a cutoff date of June 30 for application of these products on soybeans. However, IDOA will be utilizing its authority pursuant to Section 24(a) of the Federal Insecticide, Fungicide and Rodenticide Act and relevant provisions of the Illinois Pesticide Act to impose a cutoff date of June 20 for application on soybeans.

In addition to the June 20 cutoff date, IDOA also includes the following additional application restrictions for application of these products on soybeans:

- Temperature restriction of 85 degrees.
- Requirement to consult the FieldWatch sensitive crop registry www.fieldwatch.com before application.
- Prohibiting application if the wind is blowing toward any Illinois Nature Preserves Commission site that is adjacent to the proposed field of application.
- Prohibiting application when the wind is blowing toward an adjacent residential area.

These Illinois provisions were also imposed in 2020.

Other requirements in both the state and federal labels include:

- Requiring an approved pH-buffering agent, also known as a volatility-reducing agent, be tank mixed with dicamba products prior to all applications.
- Requiring a downwind buffer of 240 feet and 310 feet in areas where listed endangered species are located.
- Additional recordkeeping items.

“This decision was made after evaluating several factors, including the reduction of pesticide misuse cases involving the use of dicamba on soybeans from 2019 to 2020,” said IDOA Acting Director Jerry Costello II.

“In 2020, the department included an 85-degree temperature restriction in addition to the June 20 cutoff date, resulting in an 80% decrease in dicamba misuse complaints.”

According to IDOA, there was a record 723 dicamba-related misuse complaints in 2019 and 148 complaints in 2020 after further restrictions were put in place.

Online Training

Now that the labels are approved, the Illinois Fertilizer and Chemical Association announced online dicamba training as required on the labels will commence soon.

As soon as training becomes available, IFCA will post details on its Illinois Dicamba Training website: www.ifca.com/IllinoisDicambaTraining.

Mexico to ban GM corn by 2024

- Real Agriculture

<https://www.realagriculture.com/2021/01/mexico-to-ban-gm-corn-by-2024/>

Mexico's president has published a decree beginning the phase out of the use of glyphosate and genetically modified corn in the country.

Biosafety authorities of the country will "revoke and refrain from granting permits" for genetically modified corn, including imports.

The decree from President Andres Manuel Lopez Obrador published on December 31, 2020 cites protection of native corn varieties, biocultural wealth, rural communities, gastronomic heritage, and the health of Mexicans, as the primary reasoning.

In accordance with the government's food self-sufficiency policies, genetically modified corn authorizations will be restricted, until the supply of corn for Mexicans' diets can be replaced, no later than January 31, 2024.

The regulations also mandate a full ban of glyphosate by the same date, January 31, 2024.

Op-ed: The reckless embrace of banned pesticides in the US

- Nathan Donley and Karen McCormack, Environmental Health News

<https://www.ehn.org/banned-pesticides-allowed-in-us--2649743719.html>

There's a reason the pesticide aldicarb is banned in more than 100 countries and one of only 36 pesticides out of thousands designated as "extremely hazardous" by the World Health Organization.

It's really nasty stuff, a potent neurotoxin that pollutes groundwater, especially in areas with highly permeable soils. People, particularly children, who drink water or eat food contaminated by aldicarb are at significant risk of developmental harm.

More than a decade ago, the U.S. Environmental Protection Agency estimated that the amount of aldicarb young children and infants could be exposed to in the U.S. was already eight times greater than the amount known to cause harm. That means the use of aldicarb had likely been poisoning young children for years.

After several years of negotiations, the EPA signed a voluntary agreement in 2010 with Bayer CropScience, then the sole maker of aldicarb, to phase out production and use of the pesticide by 2018. The eight-year time frame of the phaseout left much to be desired, but the uses that posed the greatest risk to young children—on citrus and potatoes—were eliminated immediately. That made aldicarb one of only a handful of pesticides that had been actively targeted for phaseout by the EPA in the last 20 years.

But unfortunately, the troubling story of aldicarb use in the U.S. does not end there. In April 2011, several months after Bayer CropScience agreed to completely phase out production of this pesticide, another pesticide company called AgLogic LLC secured approval from the EPA for the use of aldicarb on a subset of crops like cotton, sugar beets, and sweet potatoes in the U.S. And the EPA is now considering expanding that approval even further.

Earlier this month AgLogic applied for approval of aldicarb on oranges, grapefruit, lemons, and limes in Florida and Texas, altogether accounting for about 400,000 acres of crops.

The EPA has not yet indicated whether it will approve this application. But it's hard to overstate just how outrageous it is that the agency has not only turned its back on its commitment to phasing out a pesticide with such well-documented health risks but is actually considering expanding its use on the very crops that pose the highest risk to people.

Related: Pesticide use by farmers linked to high rates of depression, suicides

The EPA's growing reputation across the globe as a pesticide pushover is highlighted by the fact that aldicarb's makers are actually arguing that one reason it would be "safe" to expand its use in the U.S. is because it cannot be used virtually anywhere else in the world.

The logic goes that since aldicarb is banned in most countries, it won't be found in imported food. Therefore, people who eat or drink a mix of imported and domestic foods will have their aldicarb exposure "diluted," so to speak.

The "It's banned everywhere else, so there's no harm in allowing its use here" approach is as shocking as it is absurd. But you'd be mistaken to think this type of argument will get the derision it deserves. The EPA has already indicated a willingness to revisit its cancellation of aldicarb based on this very argument.

The EPA's troubling decision to consider broader uses of aldicarb reflects a well-documented trend in the agency.

For example, the EPA is in the process of approving the use of up to 650,000 pounds of the medically-important antibiotic streptomycin as a pesticide on half a million acres of the same citrus trees that may be treated with aldicarb and several other new and older pesticides. By contrast, only 14,000 pounds of streptomycin's entire antibiotic class are used for human medicinal purposes each year.

EPA's reckless decision ignores the fact that streptomycin is not only considered "critically important" for human medicine by the World Health Organization, but is currently used to fight another global pandemic that kills an estimated one million people each year: tuberculosis.

The wanton overuse of human medicines to treat bacterial diseases in plants is why the U.S. Centers for Disease Control and Prevention has raised concerns over this impending approval and why the European Union, Brazil, and other nations have banned its use on plants entirely.

The overuse of antibiotics like streptomycin, which are essential to treating human disease, can threaten public health because it facilitates the growth of bacteria that have developed resistance to these medicines.

The EPA's careless approach to both aldicarb and streptomycin are symptoms of a severely broken pesticide regulatory system in the U.S.—one that instead of asking whether it should approve a dangerous pesticide, usually finds a way to greenlight any product proposed by the pesticide industry.

It is, of course, possible that a Biden Administration will step in and prevent the broader approval of aldicarb or streptomycin from ever happening. But it's also possible that, with dozens of other important environmental issues to address, coupled with a CDC overwhelmed with the pandemic and an American public conditioned to trust the EPA's judgment, that their approvals will just slide right on through.

That is the path of least resistance and business as usual in the EPA's pesticide office.

That deeply flawed regulatory process is why the U.S. allows the use of 85 pesticides, at a level of hundreds of millions of pounds each year, that have been banned or are being phased out in the European Union, China, or Brazil, according to a peer-reviewed study authored last year.

Related: Ever heard of isoxaflutole? That's about to change

It's why, just in the last few years, the EPA approved more than 100 pesticide products containing ingredients widely considered to be the most dangerous still in use, including some that were previously targeted for phaseout in the U.S. This includes two products containing methyl bromide, a potent ozone-depleting chemical that the U.S. committed to phasing out 15 years ago under the Montreal Protocol.

It's why just last fall the EPA approved several new toxic pesticides and proposed the re-approval of dozens of older toxic pesticides—including atrazine, paraquat, and multiple neonicotinoids, organophosphates, and carbamates that are known to cause serious harm to people, wildlife, and the environment.

And it's why the U.S. is widely considered by pesticide companies to be a dumping ground for the world's worst poisons. If the EPA ignores aldicarb's well-documented harm to humans and the environment and bows to the pesticide-makers' request to greatly expand its use, it will further cement our well-deserved reputation for putting pesticide company profits ahead of the health of young children and imperiled wildlife.

But before this story becomes a full reality, the Biden EPA should quickly step up and demonstrate its commitment to returning the agency to the critical job its title evokes: environmental protection.

A decision by the agency early in the new year to reject broader uses of aldicarb and streptomycin—and revisit many of the recent deplorable decisions made by EPA's pesticide program—would send an important message signaling that science, not the heavy-handed influence of agribusiness, will now drive all pesticide decisions moving forward.

EPA is taking public comment on the aldicarb application until Jan 6.

Nathan Donley, Ph.D. is a former cancer researcher who now works as a senior scientist specializing in pesticide policy at the Center for Biological Diversity. Karen McCormack, M.S. is a former pesticide researcher, policy analyst, environmental fate scientist, and communications specialist at the EPA.

Their views do not necessarily represent those of Environmental Health News, The Daily Climate, or publisher, Environmental Health Sciences.

EPA Publishes Final Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos

— Bergeson & Campbell PC

<https://www.lawbc.com/regulatory-developments/entry/epa-publishes-final-risk-evaluation-for-asbestos-part-1-chrysotile-asbestos>

The U.S. Environmental Protection Agency (EPA) released on December 30, 2020, the final risk evaluation for asbestos, part 1: chrysotile asbestos. Of the six use categories evaluated (chlor-alkali diaphragms, sheet gaskets, other gaskets, oilfield brake blocks, aftermarket automotive brakes/linings, and other vehicle friction products), EPA states that it found that there is unreasonable risk to workers, occupational non-users (ONU), consumers, and/or bystanders within each of the six chrysotile asbestos use categories. EPA found no unreasonable risk to the environment.

EPA's next step in the process required by the Toxic Substances Control Act (TSCA) is to develop a plan to reduce or eliminate the unreasonable risks found in the final risk evaluation. EPA states that it "is moving immediately to risk management for chrysotile asbestos and will work as quickly as possible to propose and finalize actions to protect against unreasonable risk." The potential actions that EPA could take to address these risks include regulating how chrysotile asbestos is used or limiting or prohibiting the manufacture, processing, distribution in the marketplace, use, or disposal of chrysotile asbestos, as applicable.

Background

TSCA Section 6, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), requires EPA to conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." The statute identifies the minimum components EPA must include in all risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. Each risk evaluation must also: (1) integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that

consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposure. The risk evaluation must not consider costs or other nonrisk factors. A detailed summary and analysis of the final risk evaluation rule is available in our June 26, 2017, memorandum, “EPA Issues Final TSCA Framework Rules.”

Risk Evaluation for Chrysotile Asbestos

The final risk evaluation states that during development of part 1, the only asbestos fiber type that EPA identified as imported, processed, or distributed under the conditions of use in the United States is chrysotile, the serpentine variety. According to the final risk evaluation, chrysotile is the prevailing form of asbestos currently mined worldwide, and “so it is assumed that a majority of commercially available products fabricated overseas that contain asbestos are made with chrysotile. Any asbestos being imported into the U.S. in articles is believed to be chrysotile.” The other five forms of asbestos are now subject to a significant new use rule (SNUR), as reported in our April 18, 2019, memorandum, “EPA Announces Final SNUR for Asbestos Will ‘Close Loophole and Protect Consumers.’”

EPA evaluated the following categories of conditions of use of chrysotile asbestos in part 1 of the risk evaluation for asbestos: importing; processing; distribution in commerce; occupational and consumer uses (use of diaphragms in the chlor-alkali industry, sheet gaskets in chemical production facilities, oilfield brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets); and disposal. The final risk evaluation states that EPA reviewed the November 2019 decision of the U.S. Court of Appeals for the Ninth Circuit in *Safer Chemicals Healthy Families v. EPA*. Part 1 of the risk evaluation for asbestos does not reflect consideration of any legacy uses and associated disposal for chrysotile asbestos or other asbestos fiber types as a result of that decision. According to the final risk evaluation, EPA intends to consider legacy uses and associated disposal and other fiber types in part 2 of the asbestos risk evaluation.

EPA made the following risk evaluation findings. EPA stated that in making these unreasonable risk determinations, it considered the hazards and exposure, magnitude of risk, exposed population, severity of the hazard, uncertainties, and other factors.

EPA found unreasonable risks to human health for uses of chrysotile asbestos:

Consumers and Bystanders: EPA found unreasonable risks to consumers and bystanders from all consumer uses of chrysotile asbestos. Most consumer products containing chrysotile asbestos have been discontinued. Consumer products still available and for which EPA found unreasonable risk include aftermarket automotive brakes/linings and certain gaskets. Risks to consumers can come from the inhalation of chrysotile asbestos; and

Workers and ONUs: Commercial chrysotile asbestos uses for which EPA found unreasonable risk to workers include chlor-alkali diaphragms, sheet gaskets, brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets. Additionally, EPA found unreasonable risks to workers nearby but not in direct contact with chrysotile asbestos for the use of chlor-alkali diaphragms, sheet gaskets, brake blocks, and other gaskets. Risks to workers and ONUs can come from the inhalation of chrysotile asbestos.

EPA found no unreasonable risks to the environment from any conditions of use. For all the conditions of use included in part 1 of the final risk evaluation, EPA found no unreasonable risks to the environment under any of the conditions of use.

Next Steps

EPA has started planning for part 2 of the risk evaluation for asbestos and will engage stakeholders as part of and following development of the draft scope document to identify any additional reasonably available information that is relevant to part 2. EPA intends to make the draft scope document available for public comment mid-year 2021. The draft scope document will be followed with a final scope document, a draft risk evaluation document for peer review and public comment, and then a final part 2 risk evaluation for asbestos. EPA states that this risk evaluation will consider chrysotile and the other five fiber types of asbestos described in the TSCA Title II definition: crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite, or actinolite.

Commentary

With the issuance of part 1 of the final risk evaluation for asbestos, risk management efforts will now commence covering the conditions of use for which EPA found unreasonable risk. EPA is required to issue a final Section 6(a) regulation within three and one half years, including potentially available extensions. In addition, for the conditions of use that were determined not to present an unreasonable risk, these decisions, which EPA issued by order under Section 6(i)(1) of TSCA, represent final agency actions that are subject to legal challenge. Generally consistent with the other risk evaluations issued to date, EPA did not evaluate hazards or exposures of chrysotile asbestos to the general population in the risk evaluation (i.e., from surface water, drinking water, ambient air, and disposal pathways) because those exposures fall under the jurisdiction of other environmental statutes administered by EPA. As a result, the unreasonable risk determinations for the relevant conditions of use do not account for these exposures to the general population.

Similarly, EPA did not evaluate hazards or exposures from chrysotile asbestos releases to terrestrial pathways for terrestrial organisms because those exposures fall under the jurisdiction of other environmental statutes administered by EPA, and as such the unreasonable risk determinations for relevant conditions of use do not account for exposures to terrestrial organisms. Considering the legal challenges filed to date on the Section 6(i)(1) orders issued as part of final risk evaluations on methylene chloride and the cyclic aliphatic bromide cluster (HBCD), legal challenges to the order may arise for the conditions of use that EPA determined do not present an unreasonable risk for reasons including EPA's exclusion of general population exposure pathways and terrestrial pathways for terrestrial organisms.

EPA was wise to split the risk evaluation between the on-going uses that it had evaluated in its draft risk evaluation from the legacy uses that EPA had not previously reviewed. This way, EPA can proceed with risk management for the on-going uses while it evaluates the potential risks from legacy uses. The alternative would necessitate that EPA delay any action on the on-going uses until it completed the entire risk evaluation. That part 2 of the risk evaluation, focusing on legacy uses and associated disposal, will likely not be completed for some time and any risk management required to address any unreasonable risks found in part 2 would not be completed for years thereafter will likely not sit well with many environmental and public health advocates, however.

As with each of the risk evaluations completed to date, EPA found a number of conditions of use that present an unreasonable risk. In this case, EPA mostly only found risk when workers use no respiratory protection. In a handful of conditions of use, EPA found risk when workers use respiratory protection with basic respiratory protection and a few conditions of use when workers use more advanced respiratory protection. Probably the most concerning condition of use is aftermarket brake and clutch replacement, especially for consumers (who tend not to use respiratory protection).

Of note, on December 22, 2020, the U.S. District Court for the Northern District of California issued a ruling pertaining to two cases, *ADAO v. EPA*, 3:19-cv-871, and *California v. EPA*, No. 3:19-cv-3807, derivative of EPA's denials of citizen petitions under TSCA Section 21 that requested EPA to collect additional information on asbestos under its TSCA Section 8(a) Chemical Data Reporting rule or a separate TSCA Section 8(a) rulemaking, respectively, to inform the on-going risk evaluation and for other purposes. After finding EPA to have acted arbitrarily and capriciously in violation of the Administrative Procedure Act in denying the petitions, the court granted the Plaintiffs' Motion for Summary Judgment and directed EPA "to amend its CDR reporting rule pursuant to its authority under 15 U.S.C. § 2607(a)(1)(A) (i.e., under Section 8(a) of TSCA), to address the information-gathering deficiencies identified herein." The deficiencies noted by the court, which the court referred to as "loopholes in the CDR reporting scheme [that] prevent EPA from receiving reasonably available information" necessary for risk evaluation and other purposes, include exemptions for asbestos when part of articles or as an impurity, and that processors are not required to report. Although the decision by the court was issued just a week before the issuance of the final part 1 of the risk evaluation, EPA's lack of any mention of the decision in the risk evaluation is somewhat puzzling. Whether EPA will appeal this decision remains to be seen; EPA has 60 days to appeal the order, so if not appealed by the Trump Administration, the decision would fall to the Biden Administration. Although the court's decision relates solely to asbestos reporting, the decision could have broader implications, including to the lengths EPA must go to obtain "reasonably available information" to inform the development of other risk evaluations.

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